

RESPONSE

1. The claims have been amended to better identify the subject matter of the present invention. Support for the amendments can be found on pages 14-16 of the specification.

2. The Applicants withdraw their objection to the Examiner's restriction requirement. Thus, claim 32 is withdrawn from examination. Claim 39 has been cancelled as this claim depends from a cancelled claim 37, as discussed below.

Claims 1, 11, and 38 have been amended to better identify the subject matter of this invention. Claims 36 and 37 have been cancelled as their limitations are now incorporated into claim 11 and 38. New claim 40 recites a claim limitation to further clarify the subject invention. Thus, claims 1, 11, 12, 30, 31, 38 and 40 are currently pending and under examination. Support for the amendments and new recitation can be found on pages 14-15 of the specification.

(2) The Examiner's rejection of claims 1, 11, 12, 30 and 31 as being anticipated by Ekpendu, et al., is respectfully traversed.

(a) The Examiner contends that that Applicants' rendering of the Examiner's reasoning is without merit. The Examiner states that "Ekpendu does not expressly teach the methanol

extract of the claim-designated plant material as an biologically active extract. However, the plant material, the source of the plant material and the solvent used in the making of the extract of the plant material are one and the same as claimed by Applicant. Therefore, a biologically active extract of the methanolic extract of the root bark of *Napoleonaea imperialis* taught by Ekpendu is inherent to the referenced extract." See: pages 3-4 of the Examiner's Office Action of August 18, 2003.

The Examiner's assertions that the source of plant material and solvent utilized in extraction is irrelevant; that all sources of the plant material are equivalent; and that the teaching of Ekpendu's root extraction inherently reads upon the present invention are respectfully traversed. In support, the Applicants respectfully draw the Examiner's attention to pages 3-4 of Dr. Okunji's 132 declaration that states, "the seeds were chosen by my group to obtain biologically active extracts showing antileishmanial activity." Furthermore, Dr. Okunji states Dr. Ekpendu, who is known to him, and Dr. Kapundu are chemists and interested in the "chemistry of this plant rather than their biological or therapeutic properties. Secondly, neither Ekpendu nor Kapundu screened for biological or pharmacological activities of the constituents of this plant. Also, both groups used similar methods in their chemical

investigation of the major constituents of *N. imperialis* known as saponins. In all, both referenced papers discussing that the saponins were first hydrolyzed before isolation and chemical identification of the constituents ... products (saponogenols/sapogenins/aglycones/genin) instead of the intact plant constituents (saponins)." These statements in Dr. Okunji's declaration are also supported by pages 14-16 of the specification.

(b) The Examiner also states that the Applicants' assertion that "Ekpendu are not directed to determining biological activity of the crude extract, but to identifying compounds present therein...that Ekpendu teaches organic solvent extracts obtained from the root bark of *N. imperialis* and not the extracts from the seeds themselves..." is unpersuasive.

Applicants have amended the claims as above to recite biological activity specific to leishmania, and have also directed claim recitation to "seeds" and "saponin extracts" commensurate with pages 14-16 of the specification. Additionally, the Examiner is respectfully requested to review pages 6-10 of Dr. Okunji's 132 declaration. Specifically, the Examiner is respectfully requested to review Dr. Okunji's discourse on "Saponin contents of different morphological plant part," and "Problems Associated with Hydrolysis: Method adopted

by Ekpendu and Kapundu." Notably, Dr. Okunji states, "saponin contents have been reported to vary depending on factors such as cultivar, the age, the physiological state and the geographical location of the plant...the saponin distribution among organs of a plant may vary considerably." See: page 6 of the attached 132 declaration.

Furthermore, the importance of the lack of hydrolysis, in accordance with the present invention (no disclosure or claim recitation of hydrolysis is made in the present invention), is further reiterated: "significant concerns such as artifacts formation, not being able to obtain genuine aglycone, possibility of epimerization, transformation, etc." See: page 7 of the attached 132 declaration. Thus, the Examiner's assertions that there is inherency of teaching of seeds due to the Ekpendu's teaching of roots, and that the mode and manner of extraction inherent by the extraction process taught by Ekpendu, et al., are scientifically incorrect. In view of the amendments to the claims and the 132 declaration, the Examiner's rejection of the claims is overcome.

(c) The Examiner's citation of Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, and MPEP §2112.01 (citing In re Best) is respectfully traversed.

(i) Atlas was directed to the issue of inherency pertaining to the term "sufficient aeration," and whether it encompassed the terms "interstitial air" and "porous air" in a explosive composition. The Court found "sufficient aeration" to be vague and established the following test for inherency: "if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated, regardless of whether it also covers subject matter not in the prior art." See Atlas at 781. Utilizing this test, the Applicants of the present invention distinguish themselves from Ekpendu, et al., as they are directed to the extraction of biologically active plant constituents, not the hydrolyzed extracts of the same. Given the chemical, biological and pharmaceutical distinctions taught by the specification, practicing the present invention does not cover the subject matter of Ekpendu et al., (or Kapundu, et al.) since Ekpendu, et al., is directed to the hydrolyzed extracts of the root bark, whereas the present invention is directed to the direct extraction (non-hydrolyzed) of seeds.

It is important to note that the excerpt cited by the Examiner is the Court's conclusion in a finding of inherency in the Atlas case. More importantly, the Court reached its conclusion based on the test recited above. Thus, applying the

Atlas test to the present issue, the present invention overcomes the test set forth in Atlas.

(ii) Additionally, the MPEP in §2112.01 states that "when the claimed and prior art products are identical or substantially identical...a prima facie case of either anticipation or obviousness has been established." Given the specification of the present invention and the disclosure of Ekpendu, et al., the Applicants strongly disagree that such a prima facie case has been established by the Examiner. Specifically, MPEP §2112.01 addresses "identical" or "substantially identical" structure or composition. The Examiner has not established a prima facie case. Rather, the Examiner has extrapolated that a teaching of hydrolyzed roots is the same as the biological extraction of seeds. Based on the specification and the 132 declaration, the Examiner's assertions are not scientifically sound, thus, a case of prima facie case has not been established.

Alternatively, MPEP §2112.01 also states that "the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed produce." As discussed above, the Applicants' specification and the 132 declaration establish that the present

invention is patentably distinguishable from the art of record. Therefore, the prima facie case, if so established, is overcome.

(iii) The Examiner's citation of MPEP §2112.01 for "product-by-process" claims is respectfully traversed.

The recited claims under examination are directed to a biologically active extract and do not recite product-by-process claims. Thus, a rejection of the claims under this is improper.

(3) The Examiner maintains her rejection of claims 1, 11, 12, 30, 31, 36-38 as being anticipated by Kapundu, et al.

(a) The Examiner's rejection is respectfully traversed. Firstly, please note that claims 36 and 37 are now cancelled. Claim 1 and 11 have been amended commensurate with the Examiner's assertion that the limitations of leishmanial activity, seed extract, and non-hydrolyzed methanol extraction are not recited in the claims. Additionally, claim 40 now recites saponin extracts as disclosed in the specification. The claim limitations overcome the Examiner's assertion that the claims of the present invention are patentably distinct from Kapundu et al.

(b) Additionally, the Examiner asserts that although Kapundu, et al., "does teach identification of compounds contained therein the methanolic seed extract, thus

necessitating a hydrolysis step of the extract, such disclosure by Kapundu does not negate the fact that Kapundu expressly teaches a methanolic extract obtained from powdered seeds of the claim-designated plant. Therefore, while Kapundu does not expressly teach that the prior art methanolic plant extract has biological activity per se, biological activity is inherent to the extract taught by Kapundu because the source of the plant, the particular plant material from the source plant, and solvent used in the making of the plant extract taught by Kapundu are one and the same." See: page 7 of the Examiner's Office Action dated June 20, 2006.

The Examiner's attention is drawn to the Applicants' 132 declaration. Applicants distinguish Kapundu, et al., by stating that the adopted hydrolysis of Kapundu, et al., incurs "significant concerns such as artifacts formation, not being able to obtain genuine aglycone, possibility of epimerization, transformation, etc." See: page 7 of the 132 declaration. This disclosure provides the necessary evidence as requested by the Examiner.

(c) Please note that, as the 132 declaration stipulates, Dr. Ekpendu is known to Dr. Okunji. It is therefore important to note that Dr. Okunji asserts that Dr. Ekpendu would have provided additional support if not for the extreme hardships

that Dr. Okunji faced in his multiple attempts to contact Dr. Ekpendu. These hardships were not economic in nature, as assumed by the Examiner, but the result of the rigors of travel to an area of the world where difficulties in communication and record keeping are impossible to overcome. Such was the nature of the hardships faced by Dr. Okunji in his bona fide attempts to provide further corroboration of the facts stipulated in his 132 declaration. Applicants are aware that, absent a showing of bad faith, 132 declarations are given the full weight of the facts stipulated therein. However, the Office is respectfully requested to give such types of hardships their due in recognition of the great lengths that Dr. Okunji underwent to promote patent protection before the United States Patent and Trademark Office.

(d) The issues raised by the Examiner regarding the Atlas Powder case and MEPE \$2112.01 with respect to her rejection of the claims under Kapundu, et al., are similar to those raised in her rejection of the claims under Ekpendu, et al. Consequently, Applicants incorporate herein their rebuttal to Examiner's arguments to Atlas Powder and MPEP \$2112.01 as discussed in Section 2(a)(i) through 2(a)(iii) above.

In view of the amendments to the claims, the 132 declaration and the response to the Examiner's assertions, the rejections to the claims have been overcome. Applicants respectfully request early allowance of the claims.

The Examiner is respectfully requested to send all correspondences to: Elizabeth, Arwine, Esq.; Office of the Staff Judge Advocate; U.S. Army Medical Research & Materiel Command; 504 Scott Street, Fort Detrick, Maryland 21702-5012: Attn: MCMR-JA (Ms. Arwine).

Please direct any questions regarding this case to Abanti Bhattacharyya, Esq., at (410) 964-9553.

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Date


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